REMARKS

Currently, claims 62-64, 66, and 69-80, including independent claim 62, are pending in the present application. Independent claim 62, for instance, is directed to a system for conducting a lateral flow assay to detect the presence or quantity of an analyte in a sample. The system comprises (a) a lateral flow membrane strip comprising a detection zone, wherein upon application, the sample is capable of traversing through the membrane strip to the detection zone and (b) reading device. The reading device includes the following components:

(1) a "housing" within which is contained an electromagnetic radiation source and a sensor capable of detecting the intensity of electromagnetic radiation.

(2) a "light barrier structure" positioned adjacent to an exterior surface of the housing. Notably, the light barrier structure defines a receiving port between a top plate and bottom plate for insertion with the membrane strip. Further, the *bottom plate* of the light barrier structure *defines an aperture through which electromagnetic radiation from the source is capable of passing* before contacting the lateral flow membrane strip. The aperture *approximates the size of the detection zone.*

(3) a "light absorbent member" positioned within the receiving port to absorb stray light, the light absorbing member comprising an absorption pad that is located adjacent to the membrane strip upon insertion into the receiving port. The absorption pad covers an area under which the membrane strip is impacted by electromagnetic radiation.

In the embodiment shown in Figs. 3-4 of the present application, for instance, the bottom plate 56 and top plate 50 define a receiving port 53 through which the lateral

flow membrane strip may be inserted. Upon insertion, light generated by a source is capable of passing through an aperture 54 to contact the strip. Further, a light absorbing member 57 is also provided in the receiving port 53. When a membrane strip is present, the light absorbing member 57 absorbs light transmitted through the strip and prevents it from being reflected back to the sensor, thereby improving the sensitivity of the reading. Secondly, when a strip is not present, the light absorbing member 57 may act as a low reflectance specimen in direct contact with the aperture 54 and thereby allow the instrument to be calibrated to eliminate the effects of internal reflections in the housing. Such calibration may therefore be performed automatically e.g., when power is first applied to the instrument, without the need to insert a calibration strip into the receiving port.

In the Office Action, independent claim 62 was rejected under *35 U.S.C. § 102(b)* as being anticipated by EP0308770 or U.S. Patent No. 4,833,088, both to DeSimone, et al.[1] DeSimone, et al. describes a measurement device having a snap action slide assembly that receives a reagent strip in an open position and then loads the strip into a measurement position wherein the strip is aligned with the read head of the device. Ambient light blocking is achieved by movement of an arm relative to the reagent strip upon closing the slide.

DeSimone, et al., however, fails to disclose multiple limitations of the present claims. For example, DeSimone, et al. describes an elastomeric light seal 70 (Fig. 5) for sealing ambient light out from the reagent area of a strip during measurement. The light seal 70 (Fig. 5) is effective when the slide assembly is closed after loading a regent strip.

---

[1] EP0308770 is the European counterpart to U.S. Patent No. 4,833,088 to DeSimone, et al.

Although the light seal 70 (shown in Fig. 5) includes a shield 78 formed by the upper arm, the shield 78 engages the reagent strip above the detection zone 22. Further, the lower arm 76 of the light seal 70 engages the strip behind the detection zone 22 and does not act as an absorption pad covering the area of the strip which is impacted by light. DeSimone, et al. explicitly teaches that the arm 76 is arranged to bias the strip against the aperture and thus a light absorption function is not contemplated. As the light shield of DeSimone, et al. does not cover and absorb light in the area opposite the aperture, it does not provide the above advantages of the present claims.

Furthermore, there is no suggestion in DeSimone, et al. to arrange a light absorbing member such that it can provide for calibration of the reading device. On the contrary, DeSimone, et al. indicates that a calibration chip is provided on the bottom of the slide assembly. When the slide assembly is opened to allow for loading of a reagent strip, the calibration chip is aligned with the read head and a calibration reading can be taken. Not only does DeSimone, et al. teach that separate calibration and light absorption means are required, but that it is advantageous to provide a calibration chip on the bottom of the slide assembly as this position avoids fouling by the samples introduced into the slide assembly. One of ordinary skill in the art would not, therefore, consider providing a calibration device inside the receiving port, let alone the possibility of using a light absorption pad for this purpose.

Thus, for at least the reasons indicated above, it is believed that the present application is in complete condition for allowance and favorable action is respectfully requested. Examiner Alexander is invited and encouraged to telephone the

undersigned, however, should any issues remain after consideration of this Amendment.

Please charge any fees required by this Amendment to Deposit Account No. 04-1403.

Respectfully submitted,

DORITY & MANNING, P.A.

Jason W. Johnston
Registration No. 45,675
P.O. Box 1449
Greenville, SC 29602-1449
Phone: (864) 271-1592
Facsimile: (864) 233-7342

Date: 2/19/08